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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,972

08/25/2006

Rene Kammerlander

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EXAMINER

SZPIRA, JULIE ANN

ART UNIT

PAPER NUMBER

3731

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DELIVERY MODE

12/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,972	Applicant(s) KAMMERLANDER ET AL.	
	Examiner JULIE A. SZPIRA	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3731

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. **Claims 18-28, 30 and 32-40 are** rejected under 35 U.S.C. 103(a) as being unpatentable over **McNicholas et al. (US 2003/0195522)** in view of **Cumming (US 5,562,731)**.

Regarding claim 18 and 38-40, McNicholas et al. discloses a device for inserting an elastically deformable intra-ocular lens into an eye, comprising: a lens holder including a base (wings; 16 and 18) that is essentially plane (the bottom of the base lays along a single plane when in an open position) which is deformable from an open position into a closed position, wherein the deformation of the elastic base increases a curvature of the intra-ocular lens disposed in the lens holder (figures 1-3); a cannula (14); and a moveable plunger (72), wherein movement of the plunger pushes the elastically deformed intra-ocular lens from the lens holder through the cannula into the eye (paragraph 37), and a tray (hinge; the lens sits upon the hinge within the base and supports the lens) but fails to disclose the base being elastic, and moving from an opened, relaxed position to a stressed, closed position.

However, Cumming teaches an elastic lens holder that has an opened, relaxed position and a stressed, closed position (column 20, lines 29-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the lens holder elastic to allow for deformation of the holder to permit a smaller profile of the holder and therefore a smaller profile of the device as a whole, which would reduce the size of the incisions made in the eye (column 7, lines 23-28).

Regarding claim 19, McNicholas et al. discloses the plunger has a free end, and wherein the free end of the plunger has an indentation running essentially in a direction transverse to the cross section of the plunger, said indentation being configured to receive an edge of the intra-ocular lens and having the form of an arc (curvilinear), a

Art Unit: 3731

radius of the arc corresponding to a bending radius of the deformed intraocular lens (paragraph 52).

Regarding claim 20, McNicholas et al. discloses a bearing part (elements 78, 80, 84 and 86) for the lens holder, said bearing part being open towards the exterior of the device.

Regarding claims 21, 22 and 35, McNicholas et al. an alignment device comprising a guide element (threads) on the plunger (Figure 4; paragraph 32).

Regarding claim 23, McNicholas et al. discloses the bearing part and the alignment device are detachably connected. The bearing part and the alignment device are coupled through the plunger rod, and when the rod is connected to the delivery device, the alignment device and bearing part are detachably connected.

Regarding claim 24, McNicholas et al. discloses the invention substantially as claimed above, but fails to disclose the bearing part and the alignment device form one piece.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the bearing part and the alignment device in one piece, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Regarding claim 25, McNicholas et al. discloses the invention substantially as claimed above, but fails to disclose the bearing part and the cannula form one piece.

Art Unit: 3731

It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the bearing part and the cannula in one piece, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Regarding claim 26, McNicholas et al. discloses the invention substantially as claimed above but fails to disclose the lens holder does not project out of the bearing part.

However, Cumming teaches the lens holder not projecting out of the bearing part (column 9, lines 30-32; The holder is held in a tied position within the delivery device).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the lens holder completely held within the bearing part to permit a smaller profile of the holder and therefore a smaller profile of the device as a whole, which would reduce the size of the incisions made in the eye (column 7, lines 23-28).

Regarding claims 27 and 36, McNicholas et al. discloses the elastic base in the stressed position forms a channel in which the curved intra-ocular lens is located (Figure 3).

Regarding claims 28 and 37, McNicholas et al. discloses the channel formed in the stressed position becomes narrower toward one end of the channel (Figure 3).

Regarding claim 30, McNicholas et al. the cross section of the bearing part having a helical cross section (the threads are helical).

Regarding claim 32, McNicholas et al. discloses the alignment device comprises at its end facing the lens holder a guide face for the plunger (the distal end of the threaded region is the end facing the lens holder and provides a guide face which interacts with the plunger).

Regarding claim 33, McNicholas et al. discloses a connecting mechanism at the lens holder in order to hold the lens holder in its closed position (paragraph 25).

Regarding claim 34, McNicholas et al. discloses a catching mechanism (interaction of wall 87 and collar 28) for positioning and holding the lens holder in its position (paragraph 35; Figure 3).

5. **Claim 29** is rejected under 35 U.S.C. 103(a) as being unpatentable over **McNicholas et al. (US 2003/0195522)** in view of **Cumming (US 5,562,731)** further in view of **Ott et al. (US 6,6447,520)**.

Regarding claim 29, McNicholas et al. in view of Cumming discloses the invention substantially as claimed above, but fails to disclose the channel having a helical cross section on the end facing the cannula.

However, Ott et al. teaches a lens holder with a channel having a helical cross section (Figure 5B).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a helical cross section to allow for a more compact folding of the IOL to lessen the size of the incision necessary for delivery of the device (column 5, lines 31-55).

Art Unit: 3731

6. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over **McNicholas et al. (US 2003/0195522)** in view of **Cumming (US 5,562,731)** further in view of **Tourrette et al. (US 2005/0125000)**.

Regarding claim 31, McNicholas et al. in view of Cumming discloses the invention substantially as claimed above, but fails to disclose the elastic base having a tapering to form a guide for the plunger.

However, Tourrette et al. teaches a tapering in the elastic base (paragraph 50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to providing a guiding taper in the elastic base to allow for the plunger to be guided into contact with the IOL (paragraph 50).

Response to Arguments

Applicant's arguments with respect to claim 18 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claim 28, the channel shown in Figure 3 of McNicholas is a cross sectional view of the device in the stressed position and the channel is tapered at the distal end, therefore meeting the limitation of the channel being narrower at one end. The first and second channels disclosed by McNicholas form a continuous lumen, and therefore the taper of the continuous channel disclosed by McNicholas meets the claim. An amendment to describe the channel as not extending past the distal end of the lens holder or some variation thereof would help overcome the prior art.

Regarding claim 33, the hinge disclosed by McNicholas does hold the lens holder in the closed position. While it is acknowledged that it doesn't hold the device *closed*, it

Art Unit: 3731

supports (of holds) the two wings in the closed position and therefore meets the limitation. Further structural limitations disclosing the connecting mechanism would help overcome the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
12/18/09